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DERWENT-ACC-NO: 1996-464768
DERWENT-WEEK: 200375
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Applied prior art
102b

TITLE: Compsns. for inducing mucosal immune response - comprising several antigenic components for admin. by different routes

INVENTOR: GUY, B; HAENSLER, J; QUENTIN-MILLET, M; QUENTIN, M M J

PATENT-ASSIGNEE: PASTEUR MERIEUX SERUMS & VACCINS SA (INMR), PASTEUR MERIEUX SERUMS & VACCINS (INMR)

PRIORITY-DATA: 1995FR-0004433 (April 7, 1995), 2000AU-0022499 (March 23, 2000)

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PATENT-FAMILY:

PUB-NO	PUB-DATE	LANGUAGE	PAGES	MAIN-IPC
<input type="checkbox"/> <u>CN 1155843 A</u>	July 30, 1997		000	A61K039/00
<input type="checkbox"/> <u>WO 9631235 A1</u>	October 10, 1996	F	058	A61K039/00
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DESIGNATED-STATES: AU CA CN HU JP MX NO NZ US AT BE CH DE DK ES FI FR GB GR IE IT LU MC NL PT SE AT BE CH DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE

CITED-DOCUMENTS:3.Jnl.Ref; GB 2220211 ; WO 9503824

APPLICATION-DATA:

PUB-NO	APPL-DATE	APPL-NO	DESCRIPTOR
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INT-CL (IPC): A61K 38/43; A61K 39/00; A61K 39/02; A61K 39/07; A61K 39/106; A61K 39/385; A61K 39/39; A61P 1/00; C12N 9/80; C12N 15/57

ABSTRACTED-PUB-NO: US 6126938A
BASIC-ABSTRACT:

Compsns. for inducing a protective immune response to an antigen at a mucosal site in a mammal comprise at least two antigenic components formulated for simultaneous or consecutive admin., the components being antigenic proteins or expression cassettes capable of expressing an antigen. One component (A) is formulated for naso-buccal admin. so as to target sites in the naso-pharyngeal region or the salivary glands. Another component (B) is formulated for mucosal (but not nasal) admin. so as to target sites where the immune response is required. An optional third component (C) is formulated for systemic admin.

USE - The vaccine compsn. is esp. for protecting against Helicobacter pylori infections of the gastrointestinal tract.

ADVANTAGE - Immunisation via multiple routes increases the immune response.

ABSTRACTED-PUB-NO: WO 9631235A
EQUIVALENT-ABSTRACTS:

Compsns. for inducing a protective immune response to an antigen at a mucosal site in a mammal comprise at least two antigenic components formulated for simultaneous or consecutive admin., the components being antigenic proteins or expression cassettes capable of expressing an antigen. One

component (A) is formulated for naso-buccal admin. so as to target sites in the naso-pharyngeal region or the salivary glands. Another component (B) is formulated for mucosal (but not nasal) admin. so as to target sites where the immune response is required. An optional third component (C) is formulated for systemic admin.

USE - The vaccine compsn. is esp. for protecting against Helicobacter pylori infections of the gastrointestinal tract.

ADVANTAGE - Immunisation via multiple routes increases the immune response.

CHOSEN-DRAWING: Dwg.0/10

DERWENT-CLASS: B04 D16

CPI-CODES: B04-B04C; B04-E03; B04-N04; B14-A01; B14-E10; D05-H07; D05-H17A5;

Hit Fwd Refs

L3: Entry 67 of 144

File: USPT

Mar 23, 2004

US-PAT-NO: 6709851

DOCUMENT-IDENTIFIER: US 6709851 B1

TITLE: Stabilization of helicobacter urease

DATE-ISSUED: March 23, 2004

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Soman; Gopalan	Belmont	MA		
Thomas, Jr.; William D.	Somerville	MA		
<u>Monath</u> ; Thomas P.	Harvard	MA		

US-CL-CURRENT: 435/227; 435/184, 435/188, 435/228, 514/2, 530/350, 530/402,
530/408, 530/409

CLAIMS:

What is claimed is:

1. A pharmaceutical composition comprising (i) a structural polypeptide of a Helicobacter urease, said polypeptide having an amino acid modification that prevents activation of said urease, and (ii) a pharmaceutically acceptable carrier or diluent.
2. The composition of claim 1, wherein said Helicobacter is Helicobacter pylori.
3. The composition of claim 1, wherein said amino acid modification is a substitution of lysine 219 of UreB.
4. The composition of claim 3, wherein said polypeptide further comprises an amino acid substitution at histidine 248 of UreB.
5. The composition of claim 3, wherein said lysine 219 is substituted with alanine or leucine.
6. The composition of claim 3, wherein said lysine 219 is substituted with alanine.
7. The composition of claim 4, wherein said histidine 248 is substituted with alanine or leucine.
8. The composition of claim 4, wherein said histidine 248 is substituted with alanine.
9. The composition of claim 1, wherein said amino acid modification is a substitution at histidine 136 of UreB.

Cite

10. The composition of claim 9, wherein said histidine 136 is substituted with alanine or leucine.
11. The composition of claim 9, wherein said histidine 136 is substituted with alanine.
12. The composition of claim 1, wherein said amino acid modification is a substitution of histidine 138, 221, 248, 274, 314, 322, or 323 of UreB.
13. The composition of claim 12, wherein said histidine is substituted with alanine or leucine.
14. The composition of claim 1, wherein said amino acid modification is a substitution at aspartate 362 of UreB.
15. The composition of claim 14, wherein said aspartate is substituted with alanine or leucine.
16. The composition of claim 1, wherein said amino acid modification is a substitution at cysteine 321 or 257 of UreB.
17. The composition of claim 16, wherein said cysteine is substituted with alanine or leucine.
18. The composition of claim 1, wherein said amino acid modification is a substitution at arginine 338 or 340 of UreB.
19. The composition of claim 18, wherein said arginine is substituted with alanine or leucine.
20. A composition comprising the polypeptide of claim 1 in a pharmaceutically acceptable carrier or diluent.
21. The composition of claim 20, further comprising an adjuvant.
22. A method of inducing an immune response to a Helicobacter in a mammal, said method comprising administering to said mammal the composition of claim 20.
23. The composition of claim 1, wherein said modification is of an amino acid that is at the active site of said urease.
24. The composition of claim 1, wherein said modification is of an amino acid that is involved in the formation of a disulfide bridge in said urease.
25. The composition of claim 1, wherein said polypeptide is recombinantly made.

First Hit Fwd Refs

L3: Entry 68 of 144

File: USPT

Dec 16, 2003

US-PAT-NO: 6663873

DOCUMENT-IDENTIFIER: US 6663873 B2

TITLE: Antigenic preparation for treatment or prevention of helicobacter infection

DATE-ISSUED: December 16, 2003

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Doidge; Christopher Vincent	Box Hill			AU
<u>Lee</u> ; Adrian	Lane Cove			AU
Buck; Fiona Jane	Malabar			AU
Pietrzykowski; Elizabeth	Essendon			AU
Quinn; Charles Alexander	Pascoe Vale			AU
Barr; Ian George	Templestowe			AU
Kleinig; Michael John	Brunswick			AU

US-CL-CURRENT: 424/234.1; 424/130.1, 424/137.1, 424/141.1, 424/150.1, 424/184.1,
424/193.1, 424/278.1, 424/283.1, 424/434, 424/93.4, 514/12, 514/2, 514/54, 977/773

CLAIMS:

What is claimed is:

1. A composition for use in the treatment or prevention of Helicobacter pylori or Helicobacter felis infection in a mammalian host by eliciting a mucosal immune response in said host, which composition comprises (A) an immunologically effective amount of an antigenic preparation comprising an at least partially purified lipopolysaccharide (LPS) of Helicobacter bacteria or an immunogenic fragment thereof which elicits said mucosal immune response, (B) a compound with adjuvant activity and (C) one or more pharmaceutically acceptable carriers or diluents.
2. A composition according to claim 1, which comprises the LPS of H. pylori or H. felis, or an immunogenic fragment thereof.
3. A composition according to claim 1, wherein the adjuvant is a mucosal adjuvant.
4. A composition according to claim 1, wherein said antigenic preparation comprises the LPS of H. pylori or H. felis.
5. A composition according to claim 1, wherein said composition comprises a purified Helicobacter lipopolysaccharide preparation.
6. A method for the treatment or prevention of Helicobacter pylori or Helicobacter felis infection in a mammalian host by eliciting a mucosal immune response in said host, comprising administering to said host an

immunologically effective amount of an antigenic preparation comprising an at least partially purified lipopolysaccharide (LPS) of Helicobacter bacteria, or an immunogenic fragment thereof, to elicit said mucosal immune response.

7. A method according to claim 6, wherein said antigenic preparation comprises the LPS of H. pylori or H. felis, or an immunogenic fragment thereof.

8. A method according to claim 6, wherein said antigenic preparation is administered in association with an adjuvant.

9. A method according to claim 8, wherein said adjuvant is a mucosal adjuvant.

10. A method according to claim 6, wherein said antigenic preparation is orally administered to said host.

11. A method according to claim 6, wherein said antigenic preparation is parenterally administered to said host.

12. A method according to claim 6, wherein said host is a human.

13. A method according to claim 6, wherein said antigenic preparation comprises a purified Helicobacter lipopolysaccharide preparation.

14. A method according to claim 6, wherein said antigenic preparation comprises the LPS of H. pylori or H.

L3: Entry 98 of 144

File: USPT

Nov 17, 1998

US-PAT-NO: 5837240

DOCUMENT-IDENTIFIER: US 5837240 A

TITLE: Multimeric, recombinant urease vaccine

DATE-ISSUED: November 17, 1998

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
<u>Lee</u> ; Cynthia K.	Needham	MA		
<u>Monath</u> ; Thomas P.	Harvard	MA		
Ackerman; Samuel K.	Weston	MA		
Thomas; William D.	Winchester	MA		
Soman; Gopalan	Belmont	MA		
Kleanthous; Harold	Allston	MA		
<u>Weltzin</u> ; Richard A.	Lunenburg	MA		
Pappo; Jacques	Newton	MA		
Ermak; Thomas	Brookline	MA		
Guirakhoo; Farshad	Melrose	MA		
Bhagat; Hitesh	Framingham	MA		
Sussman; Ilene	Newton	MA		

US-CL-CURRENT: 424/94.6; 424/234.1, 435/227, 514/925, 514/926, 514/927

CLAIMS:

What is claimed is:

1. A method of treating Helicobacter pylori infection in a patient, said method comprising administering to a mucosal surface of said patient an immunogenically effective amount of a composition comprising multimeric complexes of recombinant, enzymatically inactive Helicobacter urease.
2. The method of claim 1, wherein said composition comprises multimeric complexes comprising eight Urease A subunits and eight Urease B subunits, multimeric complexes comprising six Urease A subunits and six Urease B subunits, and/or multimeric complexes comprising four Urease A subunits and four Urease B subunits.
3. The method of claim 2, wherein said composition comprises multimeric complexes comprising eight Urease A subunits and eight Urease B subunits, multimeric complexes comprising six Urease A subunits and six Urease B subunits, and multimeric complexes comprising four Urease A subunits and four Urease B subunits.
4. The method of claim 1, wherein said mucosal surface is nasal.
5. The method of claim 1, wherein said mucosal surface is oral.

6. The method of claim 1, wherein said composition is administered without gastric neutralization.

7. The method of claim 1, wherein said multimeric complex is administered in association with a mucosal adjuvant. >

8. The method of claim 7, wherein said mucosal adjuvant is heat-labile enterotoxin of enterotoxigenic *Escherichia coli*, or a derivative thereof. >

9. The method of claim 7, wherein the mucosal adjuvant is cholera toxin, or a derivative thereof.

10. The method of claim 1, wherein said multimeric complexes of recombinant, enzymatically inactive Helicobacter urease are freeze-dried before administration.

103

DOCUMENT-IDENTIFIER: US 5690938 A

TITLE: Oral immunization with multiple particulate antigen delivery systemAbstract Text (1):

Method of inducing a mucosal and or/systemic immune response in a host, comprising the step of administering to the host an effective amount of a Bluetongue antigen in the form of virus like and/or virus core like particles. Vaccines are also provided.

INVENTOR (5):Monath; Thomas P.Brief Summary Text (12):

From the above, it will be understood that it is possible to genetically engineer proteins of completely unrelated viruses and bacteria into VLP's and CLP's. The resulting chimeric VLP's and CLP's may be used as vaccines to induce immunity against the selected agent incorporated. VLP's and CLP's composed solely of Bluetongue proteins may be used to protect animals, notably sheep, against Bluetongue virus disease, VLP's and CLP's may also be produced from viruses related to Bluetongue, especially African Horsesickness. Moreover, it is possible to incorporate foreign proteins to produce vaccines, especially oral vaccines, against diseases such as hepatitis B, Clostridium difficile, Helicobacter pylori, influenza, parainfluenza, respiratory syncytial virus (RSV), rotavirus and HIV.

CLAIMS:

1. A method of inducing a mucosal and a systemic immune response in a host, said method comprising the step of orally administering to a mucosal surface of said host a bluetongue antigen in the form of virus core like particles or in the form of virus like particles and in an amount effective to induce said immune response.

US-PAT-NO: 5690938

DOCUMENT-IDENTIFIER: US 5690938 A

TITLE: Oral immunization with multiple particulate antigen delivery system

DATE-ISSUED: November 25, 1997

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Ermak; Thomas H.	Cambridge	MA		
Pappo; Jacques	Cambridge	MA		
Guirakhoo; Farshad	Cambridge	MA		
Nichols, Jr.; Richard D.	Cambridge	MA		
<u>Monath</u> ; Thomas P.	Cambridge	MA		
Roy; Polly	Oxford			GB2

US-CL-CURRENT: 424/215.1; 435/69.3

CLAIMS:

We claim:

1. A method of inducing a mucosal and a systemic immune response in a host, said method comprising the step of orally administering to a mucosal surface of said host a bluetongue antigen in the form of virus core like particles or in the form of virus like particles and in an amount effective to induce said immune response.
2. A method according to claim 1, wherein said antigen is administered with an adjuvant.
3. A method according to claim 2, wherein said adjuvant is cholera toxin.
4. A method according to claim 1, wherein said virus core like particles comprise VP3 and VP7.
5. A method according to claim 1, wherein said virus like particles comprise VP3, VP7, VP2 and VP5.

KE LS LU MC MW NL OA PT SD SE SZ UG AT BE CH DE DK ES FI FR GB GR IE IT LI LU MC
NL PT SE

CITED-DOCUMENTS:2.Jnl.Ref

APPLICATION-DATA:

PUB-NO	APPL-DATE	APPL-NO	DESCRIPTOR
WO 9633732A1	April 25, 1996	1996WO-US05800	
AU 9655764A	April 25, 1996	1996AU-0055764	
AU 9655764A		WO 9633732	Based on
NO 9704969A	April 25, 1996	1996WO-US05800	
NO 9704969A	October 27, 1997	1997NO-0004969	
EP 831892A1	April 25, 1996	1996EP-0913166	
EP 831892A1	April 25, 1996	1996WO-US05800	
EP 831892A1		WO 9633732	Based on
CZ 9703426A3	April 25, 1996	1996WO-US05800	
CZ 9703426A3	April 25, 1996	1997CZ-0003426	
CZ 9703426A3		WO 9633732	Based on
HU 9801266A2	April 25, 1996	1996WO-US05800	
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HU 9801266A2		WO 9633732	Based on
US 5837240A	April 28, 1995	1995US-0431041	Cont of
US 5837240A	August 26, 1997	1997US-0920095	
JP 11504633W	April 25, 1996	1996JP-0532724	
JP 11504633W	April 25, 1996	1996WO-US05800	
JP 11504633W		WO 9633732	Based on
NZ 307017A	April 25, 1996	1996NZ-0307017	
NZ 307017A	April 25, 1996	1996WO-US05800	
NZ 307017A		WO 9633732	Based on
KR 99008155A	April 25, 1996	1996WO-US05800	
KR 99008155A	October 28, 1997	1997KR-0707680	
KR 99008155A		WO 9633732	Based on
MX 9708319A1	October 28, 1997	1997MX-0008319	
BR 9609871A	April 25, 1996	1996BR-0009871	
BR 9609871A	April 25, 1996	1996WO-US05800	
BR 9609871A		WO 9633732	Based on
AU 723063B	April 25, 1996	1996AU-0055764	
AU 723063B		AU 9655764	Previous Publ.
AU 723063B		WO 9633732	Based on
AU 200042567A	April 25, 1996	1996AU-0055764	Div ex
AU 200042567A	June 21, 2000	2000AU-0042567	
AU 200042567A		AU 723063	Div ex

NZ 336216A	June 10, 1999	1999NZ-0307017	Div ex
NZ 336216A	June 10, 1999	1999NZ-0336216	
NZ 336216A		NZ 307017	Div ex
CN 1188416A	April 25, 1996	1996CN-0194986	
AU 762563B	April 25, 1996	1996AU-0055764	Div ex
AU 762563B	June 21, 2000	2000AU-0042567	
AU 762563B		AU 200042567	Previous Publ.
AU 762563B		AU 723063	Div ex
MX 215310B	April 25, 1996	1996WO-US05800	
MX 215310B	October 28, 1997	1997MX-0008319	
MX 215310B		WO 9633732	Based on

AU 762563 B INT-CL (IPC): A61K 0/00; A61K 31/34; A61K 31/415; A61K 31/425; A61K 31/557; A61K 31/71; A61K 38/46; A61K 38/50; A61K 39/02; A61K 39/106; A61K 39/39; A61K 45/00; A61K 51/00; C12N 9/14

ABSTRACTED-PUB-NO: US 5837240A
BASIC-ABSTRACT:

A vaccine for inducing a mucosal immune response to Helicobacter comprises, apart from carrier or diluent, multimeric complexes (A) of recombinant, enzymatically inactive Helicobacter urease. Also new are compsns. for treating gastroduodenal infections contg.: (i) an antigen (Ag) from a gastroduodenal pathogen; and (ii) an antibiotic, antisecretory or bismuth salt.

USE - The vaccines are used to treat or prevent Helicobacter, esp. H. pylori, infections and induce a protective, secretory IgA response.

ADVANTAGE - The compsn. is more effective than either component used alone.

ABSTRACTED-PUB-NO: WO 9633732A
EQUIVALENT-ABSTRACTS:

A vaccine for inducing a mucosal immune response to Helicobacter comprises, apart from carrier or diluent, multimeric complexes (A) of recombinant, enzymatically inactive Helicobacter urease. Also new are compsns. for treating gastroduodenal infections contg.: (i) an antigen (Ag) from a gastroduodenal pathogen; and (ii) an antibiotic, antisecretory or bismuth salt.

USE - The vaccines are used to treat or prevent Helicobacter, esp. H. pylori, infections and induce a protective, secretory IgA response.

ADVANTAGE - The compsn. is more effective than either component used alone.

CHOSEN-DRAWING: Dwg.0/15

DERWENT-CLASS: B04 D16

CPI-CODES: B02-A; B02-C; B02-E; B02-T; B04-B04C1; B04-H03; B05-A01B; B07-D09; B14-S11B; D05-H07;

First Hit

L3: Entry 117 of 144

File: DWPI

Jun 10, 2003

DERWENT-ACC-NO: 2003-799824

DERWENT-WEEK: 200375

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TITLE: Inducing immune response to Helicobacter useful for treating Helicobacter pylori infection, by administering immunogenic Helicobacter polypeptide admixed with adjuvant having heat-labile toxin of Escherichia coli

INVENTOR: GUY, B; WELTZIN, R A

PRIORITY-DATA: 1999US-0336115 (June 18, 1999), 1998US-0100258 (June 19, 1998)

Search Selected

Search ALL

Clear

PATENT-FAMILY:

PUB-NO	PUB-DATE	LANGUAGE	PAGES	MAIN-IPC
<input type="checkbox"/> <u>US 6576244 B1</u>	June 10, 2003		069	A61K039/02

INT-CL (IPC): A61K 39/02

ABSTRACTED-PUB-NO: US 6576244B

BASIC-ABSTRACT:

NOVELTY - Inducing (M1) protective immune response to Helicobacter infection in a mammal comprising administering to the mammal by injection an immunogenic Helicobacter pylori polypeptide (I) comprising a subunit of H.pylori urease admixed with an adjuvant having one or more heat-labile toxin of Escherichia coli (LT), B subunit of LT (LTB), cholera toxin (CT), and B subunit of CT, is new.

ACTIVITY - Antibacterial.

MECHANISM OF ACTION - Vaccine.

No biological data given.

USE - (M1) is useful for inducing an immune response to Helicobacter infection in a mammal (claimed). (M1) is useful for both treatment and prevention of H.pylori infection.

ADVANTAGE - (M1) induces protective immune response to Helicobacter infection (claimed). The parenteral administration of LT in (M1) shows toxicity which is limited to thus the injection site swelling. The heightened effect of parenterally administering LT (low dose)+LTB (high dose) minimizes the possibility of any potential side effects.

DESCRIPTION OF DRAWING(S) - The figure shows titers of IgG to urease in sera of immunized mice.

ABSTRACTED-PUB-NO: US 6576244B
EQUIVALENT-ABSTRACTS:

CHOSEN-DRAWING: Dwg.6/11

The main effector sites at which an immune response may be sought are the respiratory system (bronchi, nasopharynx, lungs), stomach, intestine and urogenital system. In the case of the respiratory system, the third inducing agent will advantageously be formulated for administration via the pulmonary route (e.g. liposomes, microspheres, and the like). In the case of the stomach or intestine, the third inducing agent will advantageously be formulated for administration via the oral route including the intragastric route (e.g. in the presence of an enteric protection, such as liposomes, microspheres, bicarbonate or gelatin capsule). In the case of the intestine or the urogenital system, the third inducing agent will advantageously be formulated for administration via the urogenital route, for example in the form of a vaginal capsule, or via the rectal route, for example in the form of a suppository.

- 50 The second or third inducing agent may, in addition, be supplemented with an adjuvant other than liposomes or microspheres and lacking toxicity, other than the non-toxic subunits or the detoxified forms of bacterial toxins.

US-PAT-NO: 6379675

DOCUMENT-IDENTIFIER: US 6379675 B1

TITLE: Immunological combination compositions and methods

DATE-ISSUED: April 30, 2002

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Becker; Robert S.	Henryville	PA		
Huebner; Robert C.	Stroudsburg	PA		
Gray; Maryann	Bartonsville	PA		
Biscardi; Karen S.	South Sterling	PA		
Erdile; Lorne F.	Tassin la Demi Lune			FR
Guy; Bruno	Lyons			FR

US-CL-CURRENT: 424/234.1; 424/192.1, 424/193.1, 424/197.11, 424/237.1, 424/244.1, 435/69.1, 530/350

CLAIMS:

What is claimed is:

1. A method for enhancing an immunological response to an OspC antigen in a host comprising:

administering to the host at least one OspC antigen with an adjuvant; and

administering to the host a lipoprotein selected from the group consisting of OspA, recombinant OspA leader sequence/PspA, recombinant OspA leader sequence/OspC, recombinant OspA leader sequence/UreA and recombinant OspA leader sequence/UreaB, wherein said lipoprotein enhances the immunological response to the OspC antigen.

2. The method of claim 1 wherein the OspC antigen and the lipoprotein are administered simultaneously.

3. The method of claim 1 wherein the lipoprotein is naturally lipidated.

4. The method of claim 1 wherein the lipoprotein is not naturally lipidated.

5. The method of claim 1 wherein the lipoprotein is an expression product of a hybrid nucleic acid molecule, comprising a first nucleic acid sequence encoding a signal sequence of a lipoprotein and a second nucleic acid sequence encoding a mature protein, or immunogenic fragment thereof, which is heterologous to the lipoprotein encoded by the first nucleic acid sequence.

6. The method of claim 5 wherein, in the hybrid nucleic acid molecule, the signal sequence is the signal sequence of an OspA protein of a Borrelia species, and the sequences are contiguous.

7. The method of claim 6 wherein, in the hybrid nucleic acid molecule, the first nucleic acid sequence and the second nucleic acid sequence are coupled in a translational open reading frame relationship.
8. The method of claim 7 wherein, in the hybrid nucleic acid molecule, the mature protein is an OspC protein of a *Borrelia* species, or an immunogenic fragment thereof.
9. The method of claim 8 wherein, in the hybrid nucleic acid molecule, the mature protein is an OspC protein from a strain of *Borrelia burgdorferi*.
10. The method of claim 9 wherein the strain of *Borrelia burgdorferi* is selected from the B31, ACA1 and Ip90 families of strains.
11. The method of claim 1 wherein the lipoprotein is antigenic.
12. The method of claim 11 wherein the lipoprotein is OspA.
13. The method of claim 1 wherein the antigen and lipoprotein are administered mucosally.
14. The method of claim 13 wherein the antigen and lipoprotein are administered intranasally.
15. The method of claim 13 wherein the antigen and lipoprotein are administered intragastrically.
16. The method of claim 13 wherein the antigen and lipoprotein are administered both intranasally and intragastrically.
17. The method of claim 1 wherein the immunological response is therapeutic.
18. The method of claim 1 wherein the immunological response is prophylactic.
19. The method of claim 5 wherein the second nucleic acid sequence encodes the at least one antigen, whereby the method comprises administering the expression product.
20. The method of claim 8 wherein the second nucleic acid sequence encodes the at least one antigen, whereby the method comprises administering the expression product.
21. The method of claim 20 wherein the lipoprotein is OspA.
22. The method of claim 1 wherein the antigen is OspC and the lipoprotein is OspA.

L3: Entry 74 of 144

File: USPT

Jun 10, 2003

US-PAT-NO: 6576244

DOCUMENT-IDENTIFIER: US 6576244 B1

TITLE: LT and CT in parenteral immunization methods against helicobacter infection

DATE-ISSUED: June 10, 2003

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
<u>Weltzin</u> ; Richard A.	Lunenburg	MA		
<u>Guy</u> ; Bruno	Lyons			FR

US-CL-CURRENT: 424/234.1; 424/184.1, 424/236.1, 424/94.6, 514/12, 530/350, 530/403

CLAIMS:

What is claimed is:

1. A method of inducing an immune response to Helicobacter in a mammal, said method comprising administering to said mammal by injection (a) an immunogenic Helicobacter pylori polypeptide that is admixed with (b) an adjuvant comprising immunogenic Helicobacter pylori polypeptide that is admixed with (b) an adjuvant comprising one or more of (i) heat-labile toxin of Escherichia coli, (ii) the B subunit of the heat-labile toxin of Escherichia coli, (iii) cholera toxin, and (iv) the B subunit of cholera toxin.
2. The method of claim 1, wherein the polypeptide and the adjuvant are provided together in a solution.
3. The method of claim 1, wherein the polypeptide comprises Helicobacter pylori urease or a subunit or immunogenic fragment thereof.
4. The method of claim 1, wherein the heat-labile toxin of Escherichia coli and the B subunit of the heat-labile toxin of Escherichia coli are administered to said mammal.
5. The method of claim 1, wherein said injection is subcutaneous.
6. The method of claim 1, wherein said injection is intradermal.
7. The method of claim 1, wherein said Helicobacter pylori polypeptide comprises catalase or an immunogenic fragment thereof.
8. The method of claim 1, wherein said Helicobacter pylori polypeptide comprises a polypeptide selected from the group consisting of HspA, HspB, lactoferrin receptor, p76 (SEQ ID NOs:1-22), p32 (SEQ ID NOs:23 and 24), BabA, BabB, AlpA, AlpB, and immunogenic fragments thereof.
9. The method of claim 1, further comprising administering to said mammal one or more additional immunogenic Helicobacter pylori polypeptides.

10. The method of claim 9, wherein said Helicobacter pylori polypeptide is urease and said one or more additional Helicobacter pylori polypeptides is selected from the group consisting of catalase, HspA, HspB, lactoferrin receptor, p76 (SEQ ID NOs:1-22), p32 (SEQ ID NOs:23 and 24), BabA, BabB, AlpA, AlpB, and immunogenic fragments thereof.
11. The method of claim 1, wherein said Helicobacter pylori polypeptide comprises a subunit of Helicobacter pylori urease.
12. The method of claim 1, wherein said Helicobacter pylori polypeptide comprises Helicobacter pylori catalase.
13. The method of claim 1, wherein said Helicobacter pylori polypeptide comprises a Helicobacter pylori polypeptide selected from the group consisting of catalase, HspA, HspB, lactoferrin receptor, p76 (SEQ ID NOs:1-22), p32 (SEQ ID NOs:23 and 24), BabA, BabB, AlpA, and AlpB.
14. A method of inducing a protective or therapeutic immune response to Helicobacter infection in a mammal, said method comprising administering to said mammal by injection (a) a polypeptide comprising a subunit of Helicobacter pylori urease that is admixed with (b) an adjuvant comprising one or more of (i) heat-labile toxin of *Escherichia coli*, (ii) the B subunit of the heat-labile toxin of *Escherichia coli*, (iii) cholera toxin, and (iv) the B subunit of cholera toxin.

DOCUMENT-IDENTIFIER: US 5897475 A

TITLE: Vaccines comprising enhanced antigenic helicobacter spp.

DATE-ISSUED: April 27, 1999

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Pace; John <u>Lee</u>	Germantown	MD		
Walker; Richard Ives	Gaithersburg	MD		
Frey; Steven Michael	Germantown	MD		

US-CL-CURRENT: 435/252.1; 424/184.1, 424/282.1, 424/93.4

CLAIMS:

What is claimed is:

1. A vaccine comprising a Helicobacter bacterium having an enhanced antigenic property or an immunogenic fragment of said bacterium, which bacterium is harvested from a liquid culture of a Helicobacter species grown in vitro in a culture medium with a combination of conditions comprising:

a) about 0.05% to about 3% bile or about 0.025% to about 0.6% of one or more bile acids or salts thereof;

b) at a temperature between about 30.degree. C. and about 42.degree. C.;

c) in air or a gas mixture, wherein the gas mixture comprises i) about 5% to about 20% CO.sub.2 with about 80% to about 95% air; or ii) about 5% to about 10% O.sub.2 with about 10% to about 20% CO.sub.2 with about 70% to about 85% N.sub.2 ; and

d) a divalent cation chelator selected from the group consisting of 0 to about 25 .mu.M of 1,2-bis(2-aminophenoxy)ethane-N,N',N'-tetraacetic acid/acetoxymethyl ester, 0 to about 10 mM of ethylene-bis (oxyethylenenitrilo)-tetraacetic acid, and 0 to about 100 .mu.M of ethylene-bis(oxyethylenenitrilo)-tetraacetic acid/acetoxymethyl ester,

wherein said Helicobacter culture is at about early log phase, between early log phase and stationary phase, or at about stationary phase and the enhanced antigenic property is a higher level of a virulence factor associated with a higher level of adherence to a host cell when compared to the adherence ability of bacteria from a culture of the Helicobacter species grown in brain heart infusion broth supplemented with bovine calf serum.

2. A vaccine comprising a Helicobacter bacterium having an enhanced antigenic property or an immunogenic fragment of said bacterium, which bacterium is harvested from a liquid culture of a Helicobacter species grown in vitro in a culture medium with a combination of conditions comprising:

a) a divalent cation chelator selected from the group consisting of about 1.0 to about 25 .mu.M of 1,2-bis(2-aminophenoxy)ethane-N,N',N'-tetraacetic

acid/acetoxymethyl ester, about 0.5 to about 10 mM of ethylene-bis (oxyethylenenitrilo)-tetraacetic acid, and about 1.0 to about 100 .mu.M of ethylene-bis(oxyethylenenitrilo)-tetraacetic acid/acetoxymethyl ester;

b) at a temperature between about 30.degree. C. and about 42.degree. C.; and

c) in air or a gas mixture, wherein the gas mixture comprises i) about 5% to about 20% CO.sub.2 with about 80% to about 95% air; or ii) about 5% to about 10% O.sub.2 with about 10% to about 20% CO.sub.2 with about 70% to about 85% N.sub.2,

wherein said Helicobacter culture is at about early log phase, between early log phase and stationary phase, or at about stationary phase and the enhanced antigenic property is a higher level of a virulence factor associated with a higher level of adherence to a host cell when compared to the adherence ability of bacteria from a culture of the Helicobacter species grown in brain heart infusion broth supplemented with bovine calf serum.

3. The vaccine according to claim 1 or 2, further comprising a pharmaceutically acceptable carrier or diluent.

4. The vaccine according to claim 1 or 2, wherein said Helicobacter bacterium is inactivated.

5. The vaccine according to claim 4, wherein said Helicobacter bacterium is inactivated by formalin treatment.

6. The vaccine according to claim 1 or 2, wherein said vaccine is suitable for mucosal or parenteral administration.

7. The vaccine according to claim 1 or 2, further comprising an adjuvant.

8. The vaccine according to claim 1, wherein the Helicobacter species is Helicobacter pylori or Helicobacter felis.

9. The vaccine according to claim 8, wherein the Helicobacter species is Helicobacter pylori strain NB3-2 (ATCC 55714) or G1-4 (ATCC 55713).

10. The vaccine according to claim 1, wherein the combination of conditions comprises:

a) about 0.05% bile salt which is glycocholate or about 0.1 to about 0.2% bile;

b) the temperature is about 37.degree. C.;

c) in about 10% to about 20% CO.sub.2 with about 80% to about 90% air, or about 10% CO.sub.2 with about 5% O.sub.2 with about 85% N.sub.2 ; and

the culture is at about log phase.

11. The vaccine according to claim 10, wherein the Helicobacter species is Helicobacter pylori or Helicobacter felis.

US-PAT-NO: 5871749

DOCUMENT-IDENTIFIER: US 5871749 A

TITLE: Therapeutic treatment of H. pylori associated gastroduodenal disease

DATE-ISSUED: February 16, 1999

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Doidge; Christopher Vincent	Box Hill			AU
Lee; Adrian	Lane Cove			AU

US-CL-CURRENT: 424/234.1; 424/194.1, 435/7.21

CLAIMS:

We claim:

1. A method for the treatment of a pre-existing Helicobacter infection in a mammalian host, which comprises mucosal administration to the infected host of (a) an immunologically effective amount of one or more Helicobacter antigens, in association with (b) a mucosal adjuvant, wherein said administration of (a) in association with (b) eradicates or suppresses the pre-existing infection in the host.
2. A method according to claim 1, wherein said one or more Helicobacter antigens comprise one or more H. pylori antigens.
3. A method according to claim 1, wherein said one or more Helicobacter antigens comprise one or more H. felis antigens.
4. A method according to claim 1, wherein said one or more Helicobacter antigens are provided by a sonicate of Helicobacter cells.
5. A method according to claim 1, wherein said adjuvant is cholera toxin or E. coli heat labile toxin.
6. A method according to claim 1, wherein said infected host is an infected human.
7. A method according to claim 1, wherein the mucosal adjuvant has mucosal delivery activity.
8. A method according to claim 1, further comprising the step of detecting a therapeutic effect in said infected host.
9. A method according to claim 1, further comprising administration of an antibiotic to the infected host.
10. A method for the treatment of a pre-existing Helicobacter infection in a mammalian host, which comprises oral administration to the infected host of (a) an immunologically effective amount of one or more Helicobacter antigens, in association with (b) a mucosal adjuvant, wherein said administration of (a)

in association with (b) eradicates or suppresses the pre-existing infection in the host.

11. A method according to claim 10, wherein said one or more Helicobacter antigens comprise one or more H. pylori antigens.

12. A method according to claim 10, wherein said one or more Helicobacter antigens comprise one or more H. felis antigens.

13. A method according to claim 10, wherein said one or more Helicobacter antigens are provided by a sonicate of Helicobacter cells.

14. A method according to claim 10, wherein said adjuvant is cholera toxin or E. coli heat labile toxin.

15. A method according to claim 10, wherein said infected host is an infected human.

16. A method according to claim 10, wherein the mucosal adjuvant has mucosal delivery activity.

17. A method according to claim 10, further comprising the step of detecting a therapeutic effect in said infected host.

18. A method according to claim 10, further comprising administration of an antibiotic to the infected host.

19. A method according to claim 11, wherein said one or more Helicobacter antigens is selected from the group consisting of H. pylori urease, H. pylori cytotoxin, H. pylori cytotoxin associated immunodominant antigen, and H. pylori heat shock protein.

20. A method according to claim 10, wherein said one or more Helicobacter antigens is selected from the group consisting of H. pylori urease, H. pylori cytotoxin, H. pylori cytotoxin associated immunodominant antigen, and H. pylori heat shock protein.

Vaccines of the present invention may be administered locally and/or systemically by any method known in the art, including, but not limited to, intravenous, subcutaneous, intramuscular, intravaginal, intraperitoneal, intranasal, oral or other mucosal routes.

US-PAT-NO: 6126938

DOCUMENT-IDENTIFIER: US 6126938 A

TITLE: Methods for inducing a mucosal immune response

DATE-ISSUED: October 3, 2000

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
<u>Guy</u> ; Bruno	Lyons			FR
<u>Haensler</u> ; Jean	Saint-Genis-les-Ollieres			FR
Quentin-Millet; Marie-Jose	Villeurbanne			FR

US-CL-CURRENT: 424/184.1; 424/199.1, 424/234.1, 424/278.1, 424/282.1, 424/812, 514/44

CLAIMS:

What is claimed is:

1. A method for inducing in a mammal, an immune response against an antigen of a pathogen of the respiratory, gastrointestinal, or genitourinary tract at mucosal effector site, which comprises administering a second and a third inducing agent, to said mammal;

wherein said second and third inducing agents are selected independently from the group consisting of the antigen and, provided the antigen is a protein, an expression cassette capable of expressing the antigen in said mammal;

wherein said second inducing agent is administered concomitantly with or prior to the third inducing agent;

wherein said second inducing agent is administered by the nasal or buccal route so that the second inducing agent is targeted to the inducer site(s) for an immune response in the naso-oropharynx or the salivary glands; and

wherein said third inducing agent is administered by a mucosal route other than the nasal route so that the antigen is targeted to the inducer site(s) for the immune response at the effector site at which the immune response is sought.

2. A method according to claim 1, wherein the antigen is a protein.

3. A method according to claim 2, wherein said inducing agent is selected from the group consisting of the antigen and an expression cassette comprising DNA encoding the antigen.

4. A method according to claim 1, wherein the third product is formulated for pulmonary administration.

5. A method according to claim 1, wherein the third product is formulated for urogenital administration.

6. A method according to claim 1, wherein the third product is formulated for

oral administration.

7. A method according to claim 6, wherein the antigen is Helicobacter pylori antigen.

8. A method according to claim 7, wherein the antigen is the apoenzyme form of H. pylori urease.

9. A method according to claim 1, wherein the third product is formulated for intragastric administration.

10. A method according to claim 9, wherein the antigen is Helicobacter pylori antigen.

11. A method according to claim 10, wherein the antigen is the apoenzyme form of H. pylori urease.

12. A method according to claim 1, wherein the first product further comprises an adjuvant selected from the group consisting of aluminum hydroxide, aluminum phosphate, and ISCOMs.

13. A method according to claim 1, wherein the second product comprises particles selected from the group consisting of liposomes and microspheres.

14. A method according to claim 13, wherein the particles are from about 0.05 μm to about 5 μm in diameter.

15. A method according to claim 1, wherein the third product comprises particles selected from the group consisting of liposomes and microspheres, and further wherein said third product is formulated for pulmonary, oral, or intragastric administration.

16. A method according to claim 15, wherein the third product comprises particles from about 0.05 to about 5 μm in diameter, and is formulated for pulmonary administration.

17. A method according to claim 16, wherein the second or third product is a spray or an aerosol.

18. A method according to claim 15, wherein the third product comprises particles from about 0.05 to about 5 μm in diameter, and is formulated for oral or intragastric administration.

19. A method according to claim 1, wherein the third product is an enterically protected preparation.

20. A method according to claim 1, wherein the second or third product further comprises a non-toxic adjuvant, other than the non-toxic subunits or the detoxified forms of bacterial toxins and other than liposomes or microspheres.

21. A method according to claim 1, wherein the second or third product further comprises the major lipopolysaccharide antigen of a bacteria.

22. A method according to claim 1, wherein the inducing agent contained in the first, the second or the third product is the antigen.

23. A method according to claim 1, wherein the inducing agents contained in the second and third products are the same.
24. A method according to claim 1, wherein the inducing agents contained in the first, second and third products are the same.
25. A method according to claim 1, wherein the antigen is pathogenic for the mammal.
26. A method according to claim 11, which comprises administering a first inducing agent to said mammal by the systemic route; said first inducing agent being selected from the group consisting of the antigen and, provided the antigen is a protein, an expression cassette capable of expressing the antigen in a mammal.
27. A method according to claim 2, wherein the first product is formulated for parenteral administration.
28. A method according to claim 27, wherein the first product is formulated for subcutaneous, intradermal or intramuscular administration.

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TITLE: Vaccine for inducing mucosal response to Helicobacter - contg. multimeric urease complex and pref. an antibiotic, anti-secretory agent or bismuth salt

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